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510(k) Summary

Date Summary Prepared	September 20, 2012
Purpose of Submission	To obtain clearance for a line extension to the existing suture devices
Manufacturer/Distributor /Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Ivette Galmez Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1263 Fax: 239/598.5508 Email: ivette.galmez@arthrex.com
Trade Name	***Arthrex Suture***
Common Name	Non-absorbable Surgical Suture
Product Code - Classification Name	GAT - 21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
Predicate Devices	*K041553 - Arthrex FiberWire and FiberTape* *K100652 - ACL TightRope*
Device Description	The ***Arthrex Suture*** is a dyed or non-dyed braided suture construct made of 100% UHMWPE. The Arthrex Suture strands that are dyed black are made of nylon. Suture ends are stiffened with cyanoacrylate. The Arthrex Suture will be supplied in pre-cut lengths with or without various swaged needles. The Arthrex Suture constructs meet USP standards for suture. The Arthrex Suture is available in straight and loop configurations; and sizes #2 to #5 for suture, and 1.5mm to 4mm (width) for tape.
Indications for Use	The ***Arthrex Suture*** is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.
Substantial Equivalence Summary	The ***Arthrex Suture*** is substantially equivalent to the predicate devices in which the basic features (design configuration, size and width) are similar and the intended use is the same.

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Substantial Equivalence Summary (continue)	The main differences between the predicate (FiberWire/FiberTape) and the proposed devices are: • FiberWire is made of UHMWPE and polyester, the proposed device is made of UHMWPE only. • FiberWire does not meet the diameter as per USP standards, the UHMWPE suture meets USP. • FiberWire sizes range from 4-0 to #5, the UHMWPE suture ranges in size from #2 to #5. • FiberTape sizes range from 2mm to 4mm, the UHMWPE tape ranges in size from 1.5mm to 4mm. • FiberTape ends taper into suture-like strands but the ends of the UHMWPE tape do not. These differences are considered minor and do not raise questions concerning safety and effectiveness. The mechanical testing demonstrates that the proposed device meets or exceeds the established minimum acceptance criteria for tensile (pull-out) strength and knot pull for the desired indications. Based on the indication for use, technological characteristics, and summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Suture*** is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 2 5 2012

Arthrex Incorporation
% Ms. Ivette Galmez
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

Re: K122374
Trade/Device Name: Arthrex Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) sur-gical suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 10, 2012
Received: September 13, 2012

Dear Ms. Galmez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

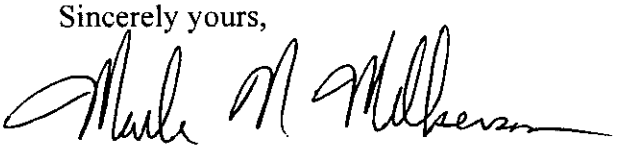
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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3 Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: ***Arthrex Suture***

Indications For Use:

The Arthrex Suture is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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